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September 18, 2024

The Honorable Georgette Castner, U.S.D.J.
United States District Court
District of New Jersey - Trenton
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

RE: Hannah Lovaglio, et al. v. Kaitlan Baston et al.
Civil Action No: 3:23-cv-21803

Dear Judge Castner:

In response to Your Honor's September 11, 2024 Order, please accept this correspondence as the Newborn Screening Alliance's interest in appearing as amicus in the above-captioned matter.

The Newborn Screening Alliance ("NSA") is a non-profit 501(c)(3) organization dedicated to the advocacy of nationwide newborn screening as well as the advancement of treatable and preventable conditions. In that regard, the NSA interacts with state and federal organizations, clinicians and patient advocacy groups to help facilitate and implement guidelines and recommendations for newborn screening.

Newborn screening ("NBS") is a state-based public health activity, supported by the federal government, that first began in or around the 1960s. Today, nearly all of the 3.65 million babies born annually in all 50 states are newborn screened. The test is simple and non-invasive. A few drops of blood are taken from the baby's heel within two (2) days of the baby's birth and added to an NBS blood spot card, which is sent to the state's lab and tested for conditions that comprise the state's newborn screening panel. The conditions on the state newborn screening panels require immediate detection and medical intervention in order to prevent life-altering and irreversible consequences, including death. Newborn screening not only saves lives, but also saves millions of dollars for our healthcare system and taxpayers by preventing severe and permanent disabilities through early detection and treatment.

In New Jersey, NBS blood spot cards play a critical role in public health and rare disease research beyond their initial diagnostic use. The blood spot cards are used to research potential lifesaving treatments as well as for quality assurance, such as the testing and validation of newborn screening

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equipment, ensuring the accuracy of newborn screening tests, improving existing newborn screening tests and developing new newborn screening tests for additional conditions. As detailed in defendants' brief, strict and effective policies exist to ensure the safety and proper use of the blood spot cards. Without the retention of dried blood spot cards, the effectiveness of current screening would be diminished and the progress of future screening would be halted.

The NSA¹ has successfully advocated for the implementation of newborn screening in 38 states, including but not limited to the addition of the last four (4) conditions to New Jersey's newborn screening panel: X-linked Adrenoleukodystrophy ("X-ALD"), Mucopolysaccharidosis type I ("MPSI"), Glycogen storage disease type II (also known as "Pompe disease") and Spinal Muscular Atrophy ("SMA"). Existing blood spot cards were used to validate all of these conditions in order to officially add them to the New Jersey state newborn screening panel, resulting in at least 29 babies having been diagnosed with said conditions since their addition. Without the crucial diagnoses provided via newborn screening for these conditions, these 29 New Jersey babies would not have received timely treatment, resulting in permanent and significant disability or even death.

Plaintiffs in this case seek to mandate the prompt destruction of New Jersey's newborn screening blood spot cards, despite the fact that their retention under current policies provides clear and tangible benefits to the public health without impeding the rights of parents and children. As an organization with extensive experience in newborn screening in this State and nationwide, the NSA is well-positioned to address these issues. Specifically, the NSA is uniquely equipped to provide firsthand accounts from individuals deeply impacted by newborn screening and the lack of newborn screening. No party in this case can provide this perspective, and it is important that it be considered in connection with balancing parental rights with the necessity of retaining blood spot cards for validation and research.

For these reasons, the NSA respectfully submits that its interest warrants an amicus curiae appearance in this matter.

Respectfully submitted,

MADDEN & MADDEN, P.A.



Regina M. Philipps

cc: Elisa Seeger (via email)

¹ Through its sister organization, the ALD Alliance, which shares the same founder, Elisa Seeger.